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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,379	10/09/2003	Luis De Taboada	ACULSR.005CP1	6100

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EXAMINER

SHAY, DAVID M

ART UNIT	PAPER NUMBER
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3735

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/682,379	TABOADA ET AL.	
	Examiner	Art Unit	
	david shay	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on August 23, 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21,23-26,28-30,37-41,44-46 and 50-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21,23-26,28-30,37-41,44-46 and 50-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>August 23, 2006</u> .   | 6) <input type="checkbox"/> Other: _____                          |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 23, 2006 has been entered.

Applicant has submitted a Declaration pursuant to 37 C.F.R. 1.132, asserting the non-obviousness of the claimed invention. Paragraph 1 establishes Declarant as one of the instant co-inventors. In paragraph 2 of the Declaration, Declarant establishes familiarity with the rejection set forth in the previous office action and the references upon which the rejection is predicated. Ensuing paragraphs 3-7, in short delineate Declarant's view that none of the prior art applied to the claims disclose or suggest "irradiating a portion of the patient's brain approximately 2 centimeters below the dura with light having a power density between about 0.01 mW per square centimeter and about 100 mW per square centimeter." While generally the examiner does not dispute these statements with respect to the references to Chess, Streeter, and Tatebayashi, the statements with respect to Oron bear closer scrutiny.

In paragraph 5, Declarant attempts to dismiss the teachings of Oron, which clearly show the desirability of irradiating rat brain tissue with power densities in the claimed range, by noting that no part of the rat's brain is at the claimed depth. While technically correct, this conclusion ignores the teachings the Oron would provide to one of ordinary skill in the art. As the instant invention is directed to "phototherapy of brain tissue affected by stroke" (see the instant specification, page 1, paragraph [0002]), one of ordinary skill in the art must be a person familiar with clinical practices of brain therapy and (since one of ordinary skill in the art will have read

articles in professional journals regarding the development of new therapies or the evaluation of the usefulness of established therapies) the methods of brain therapy evaluation and their development. Being so familiar, one of ordinary skill in the art will immediately realize that Oron's tests on rats were done because rats are good clinical models for the effects various therapies will have on humans, and thus the desired therapeutic doses of light for the rat will be similar for the human, which does have portions of the brain which are more than 2 cm below the dura, which may require therapy.

In paragraph 6, Declarant attempts to dismiss the teachings of Oron, with regard to the light transmission properties of the human skull. Declarant notes that Oron does not discuss whether or not the brain was in the skull at the time of the test. This ignores the teachings set forth within the four corners of the Oron references and the inferences that one of ordinary skill in the art would draw therefrom. Since Oron is specifically concerned with phototherapy of the brain, the issue is not whether or not a human brain was irradiated during the test discussed at column 6, lines 17-39. The issue is the fact that Oron clearly desires to irradiate the human brain with at least the power density disclosed in column 6, lines 17-39 (note the comment that higher better penetration could be achieved at locations where the skull is thinner at lines 28-31 of that passage). This is also evidenced by then power densities used on the rat brain as set forth above. Thus Delcarant's conclusion that Oron does not disclose or suggest the claimed power density is not convincing in view of the fact that this suggestion is made to one of ordinary skill in the art.

Paragraphs 8 and 9 assert "substantial advantages that were unexpected in view of previous work", however, these paragraphs only discuss that an effect over and above the

placebo affect is achieved with the irradiation employed therein. This is not seen as unexpected given that the irradiation of Oron is disclosed as having a therapeutic effect in and of itself.

The remainder of the Declaration deals with experimental data indicating the percentage of transmission of light through the skull (paragraph 10). Which, the examiner notes, agrees generally with the power densities transmitted as determined by Oron. And discusses in paragraph 11 the intensity produced at various depths in the brain (none of which are 2 cm.). Declarant then concludes in paragraph 12, that the evidence provided shows that the intensities produced by the unpublished study referenced in paragraph 9 fall within the claimed parameters, and in paragraph 13 concludes that there is therefore an unexpected beneficial result. This conclusion is faulty for the same reasons set forth with respect to the same conclusion based on the showing of paragraph 9 and is therefore not convincing.

Applicant's arguments, which are predicated on the flawed conclusions arrived at in the instant Declaration, are not convincing for the same reasons as the Declaration.

The amendment filed August 23, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: providing an irradiance at the surface of the scalp is between about  $10 \text{ mw/cm}^2$  and  $10 \text{ W/cm}^2$  to produce an irradiance of about  $0.01 \text{ mw/cm}^2$  and  $100 \text{ mw/cm}^2$  at a depth of 2 cm below the dura.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 59 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification. The originally filed disclosure and the disclosure as amended is silent on providing an irradiance at the surface of the scalp is between about 10 mw/cm<sup>2</sup> and 10 W/cm<sup>2</sup> to produce an irradiance of about 0.01 mw/cm<sup>2</sup> and 100 mw/cm<sup>2</sup> at a depth of 2 cm below the dura.

Claims 1-6, 8-10, 14, 19, 23-26, and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Oron in view of Chance et al.

Diode lasers inherently produce a small continuum of frequencies and thus produce plural wavelengths. Any slight delay in the actuation of the lasers will result in one wavelength being delivered subsequent the other. Oron clearly intends to treat the brain. Further, Oron states that penetration of the laser energy should be better at a thinner portion of the skull, clearly demonstrating that one having ordinary skill in the art understands that higher irradiation intensities are desirable. As can be seen from the Chance et al article (supplied herewith), the absorption slope ( $\mu$ ) of the skull is approximately 0.088 cm<sup>-1</sup> (see page 4972, column 1, third paragraph under METHODS, and page 4973, Table 1). Given the relationship of  $\mu$  to the intensity ratio (see equation [6] at the top of page 4972), the relative intensity passing through the skull would be 3.5 mw/cm<sup>2</sup> however, since the area also increased by a factor of about 300, this indicates that the irradiance at the outside of the skull is about 1 W/cm<sup>2</sup>. Given that applicant claims that the irradiance at the surface of the scalp is between about 10 mw/cm<sup>2</sup> and 10 W/cm<sup>2</sup> (see claim 59) and since this claim depends from a claim that requires the claimed

irradiance at 2 cm below the dura, the irradiance of Oron must also produce an irradiance in the claimed range at that depth.

Claims 37, 38, 44-46, 51-54, and 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oron in combination with Chance et al and Streeter ('451). Oron teaches a device as set forth above. Streeter ('451) teaches the desirability of blanching the scalp before providing phototherapy. It would have been obvious to the artisan or ordinary skill to transmit the light through blanched tissue in the method of Oron, since this allows more light to penetrate to the injury, as taught by Streeter ('451), thus producing a method such as claimed.

Claims 7, 15-18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oron in combination with Chance et al, Eckhouse, and Chess. Oron teaches a device such as claimed except for the use of cooling (please note that the absence of cooling or the use of cooling implies the absence of other structures predicated thereon, such as the use of a particular coolant). Eckhouse teaches that for the intensities applied to the epidermis that Oron uses to provide therapeutically effective amounts of radiation to the brain, require cooling to prevent epidermal damage. Chess teaches the equivalence of various cooling schemes to prevent damage to overlying tissues. It would have been obvious to the artisan of ordinary skill to employ cooling in the device and method of Oron, since the intensities that Oron must use to provide therapeutically effective amounts of radiation to the brain, require cooling to prevent epidermal damage, as taught by Eckhouse, and to employ the various cooling devices and steps taught by Chess, since these are equivalents for the purposes of providing sufficient cooling to spare overlying tissues, as taught by Chess and to employ air as the coolant, since Chess teaches that

any transparent gas can be used, and air is readily available and provides no unexpected result, thus producing a device such as claimed.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oron in combination with Chance et al and Eckhouse. Oron teaches a device such as claimed except for the use of cooling (please note that the absence of cooling or the use of cooling implies the absence of other structures predicated thereon, such as the use of a particular coolant). Eckhouse teaches that for the intensities applied to the epidermis that Oron uses to provide therapeutically effective amounts of radiation to the brain, require cooling to prevent epidermal damage. It would have been obvious to the artisan of ordinary skill to employ cooling in the device and method of Oron, since the intensities that Oron must use to provide therapeutically effective amounts of radiation to the brain, require cooling to prevent epidermal damage, as taught by Eckhouse, and to employ gel, since this provides sufficient cooling for these intensities, as also taught by Eckhouse, thus producing a device such as claimed.

Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oron in combination with Chance et al, Eckhouse, Meserol, and Kuesch et al. Oron teaches a device such as claimed except for the use of cooling (please note that the absence of cooling or the use of cooling implies the absence of other structures predicated thereon, such as the use of a particular coolant, e.g. glycerol). Eckhouse teaches that for the intensities applied to the epidermis that Oron uses to provide therapeutically effective amounts of radiation to the brain, require cooling to prevent epidermal damage. Meserol teach a device for applying light to the skin wherein the transmission of the light is enhanced by hydrating the skin. Kuesch et al teach producing skin hydration using glycol. It would have been obvious to the artisan or ordinary



skill to employ glycol as taught by Kuesch et al in the method of Oron, since this is warranted for the intensities used, as taught by Eckhouse, and since glycerol increases the transmission of laser light through the skin surface, as taught by Meserol, and thus requires less power to treat the injury, thus producing a device and method such as claimed.

Claim 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oron in combination with Chance et al Rosen et al and Meserol. Oron teaches a method as claimed except for the electroluminescent sheet. Rosen et al teach the use of a sheet of material including electroluminescent devices and teaches that optical fibers are also used in the prior art. Meserol teaches the use of a reflective coating to direct reflected light back to the skin. It would have been obvious to the artisan of ordinary skill to employ the electroluminescent sheet of Rosen et al in the method of Oron, since this also provides large area coverage, or to employ woven optical fibers, since these are known light emitting sheet material used for light application, and are not critical, and in either case to provide a reflective coating as taught by Meserol, since this will redirect reflected light back to the skin, as thus producing a method such as claimed.

Claim 55, 56, and 60-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oron in combination with Chance et al and Lo et al. Oron teaches a method as claimed except for the specific intensity, treatment interval, and treatment time. Lo et al teach that times several hours after the injury are among the ideal times to provide treatment. It would have been obvious to the artisan of ordinary skill to employ the claimed intensities, treatment intervals, and treatment times in the method of Oron, since these are known light intensities and treatment times for laser therapy, are not critical, and produce no unexpected result, and to estimate the time of the ischemic event, then begin delivering light to the stroke victim several hours after the

ischemic event in the method of Oron, since this is a good time to begin treatment, as taught by Lo et al and since these times are not critical, thus producing a method such as claimed.

Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oron in combination with Chance et al, Streeter ('451) and Mueller et al. Oron teaches a method as claimed except for the electroluminescent sheet. Streeter ('451) provides the teachings set forth above. Mueller et al teach the use of ultrasound in combination with laser light to encourage revascularization. It would have been obvious to the artisan of ordinary skill to employ the ultrasound and laser combination of Mueller et al in the method of Oron, since this enables revascularization, which would mitigate the effects of ischemia, since the new blood vessels would be able to deliver oxygen to the affected tissues, and in either case to transmit the light through blanched tissue, since this allows more light to penetrate to the injury, as taught by Streeter ('451), thus producing a method such as claimed.

Applicant's arguments filed August 23, 2006 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

Applicant's arguments with respect to claims 1-21, 23-26, 28-30, 37-41, 44-46, and 50-66 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and

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Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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